

REMARKS

Claims 1-10 are pending. Claims 6 -10 are withdrawn from further consideration in response to a restriction requirement as being drawn to a non-elected invention. Applicant respectfully traverses the rejections in the outstanding Office Action, and submits that Claims 1-5 contain patentable material in view of the following Remarks.

Election/Restrictions

Claims 1-5, drawn to a method for increasing the throughput of a clinical analyzer and identified as Invention I, and claims 6-10, drawn to an analytical analyzer and identified as Invention II are said to be distinct under MPEP §806.05(e). In response to a restriction requirement under 35 USC 121, Applicant hereby elects Invention I, claims 1-5, as the elected Invention to be examined without traverse. Claims 6-10 are withdrawn from further consideration under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claim Rejections – 35 USC §102

Claims 1 and 5 stand rejected under 35 USC 102(b) as being anticipated by Bell (U. S. 5,679,309). Regarding Claim 1, the Examiner cites Bell for allegedly disclosing a method to increase analyzer throughput “using reagents inventoried in at least two servers (combination of **30** and **46** and **22**).” Regarding Claim 5, the Examiner cites Bell for allegedly disclosing “selecting reagents from whichever of the two (reagent) servers has the shorter backlog of demand with which to perform assays in the first pattern of assays”.

Applicant respectfully disagrees with the Examiner because these citations of Bell reflect an inaccurate understanding of Bell’s clinical analyzer 10 as compared to the claimed invention for at least the following reasons.

FIRST: Fig. 2 illustrates a sample wheel 20 disposed adjacent to an analysis carousel **22** having a number of re-usable cuvettes 24 adapted to receive reactants

and sample for analysis. (Col. 5, lines 49-56). In addition, a reactant wheel **26** is disposed adjacent to the analysis carousel **22** having containers 28 with reactant therein (Col. 6, lines 16-23). A sample transfer station **30** moves a sample probe 32 in an arc intersecting the sample wheel 20 and a cuvette 24 on analysis carousel **22** (Col. 6, lines 35-42). Similarly, a reactant transfer station **46** moves a reactant probe 50 in an arc 58 intersecting containers 28 on the reactant carousel **26** and reactant addition points 59a and 59b on analysis carousel **22** (Col. 7, lines 11-25). In other words, sample transfer station **30** and reactant transfer station **46** and analysis carousel **22** combine to do no more than transfer sample to be tested from sample vials 18 into a cuvette 24 and to transfer requisite reactants from a reactant wheel 26 into the cuvette 24 so that an analysis of the sample may take place. In contrast to the Examiner's statement, Bell does not disclose "reagents inventoried in at least two servers" because there is only one reactant wheel **26** in Bell's analyzer.

Because Bell discloses only one single reactant wheel **26**, it cannot be said that Bell anticipates Applicant's method for increasing the throughput of a clinical analyzer by duplicating reagents within at least two reagent servers as is claimed in Claim 1. For this first reason, Applicant submits that the outstanding rejection under 35 USC 102(b) as being anticipated by Bell is improper and should be withdrawn.

SECOND: Bell is attempting to increase analyzer throughput by increasing the frequency at which washing a used cuvette can take place simultaneously with the addition of reactant to a target cuvette. (SUMMARY at Col. 2, lines 62-67 and Col. 3, lines 51-54) This is accomplished by adding a second reactant add station (A second reactant add station is NOT a second reactant wheel) so that reactant can be added to a target cuvette at either of two separate locations on a reaction carousel. (Col. 3, lines 32-33)

As described in FIG. 5, and Col. 3, lines 32-58, because of the circular nature of the reactant carousel **26**, if the target cuvette is positioned at a first reactant add station, then a first cuvette is parked within a wash station . . . but if the target cuvette is positioned instead at a different reactant add station, then a different cuvette is parked within the wash station. For example:

At Event 1, Cuvette C1 is positioned at reactant add station R1 and a corresponding Cuvette C2 is parked at wash station WS.

At Event 2, Cuvette C1 is instead positioned at reactant add station R2 and a corresponding different Cuvette C3 is parked at wash station WS.

What Bell teaches is to position Cuvette C1 at whichever reactant add station R1 or R2 places a used cuvette ready for washing at the wash station WS. This is described at Col. 10, lines 20-24:

“the processor identifies cuvettes 24 which are available for reactant addition in comparison to the inventory of wash-ready cuvettes. Based upon this comparison, the processor determines whether to add reactant at either the first or second reactant addition points which will locate, during the same park cycle, a wash-ready cuvette at the wash point.”

If neither Cuvette C2 nor Cuvette C3 is ready to be washed, Bell teaches “Do Not Wash Cuvette” (114 in FIG. 5).

In other words, Bell does no more to increase analyzer throughput than to add reactant at whichever of two reactant add stations opportunistically places a used cuvette at a wash station so that washing and reactant addition can take place simultaneously. This is not “selecting reagents from whichever of the two (reagent) servers has the shorter backlog of demand with which to perform assays in the first pattern of assays” as the Examiner has stated.

The MPEP makes it clear at 706.02 V (page 700-23) that for an anticipation rejection under 35 U.S.C. 102(b) to be valid, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. For at least the two reasons given above, Bell does not explicitly or impliedly teach the features of Claims 1 and 5. Furthermore, Bell does not inherently even require that the features of Claims 1 and 5 be present to practice his invention since only the single reactant carousel **26** is needed. In contrast, Applicant's

method for increasing the throughput of a clinical analyzer requires at least two reagents servers as claimed in Claim 1.

Applicant submits that Bell's analyzer cannot be operated to conduct Applicant's claimed invention, thereby rendering the rejection moot, and respectfully request that the rejection of Claims 1 and 5 under 35 USC 102(b) as being anticipated by Bell be withdrawn.

Claim Rejections –35 USC §103(a)

Claims 2-4 are rejected under 35 USC 103(a) as being unpatentable over Bell (US 5,679,309). The Examiner recognizes that Bell does not disclose "a first pattern of assays having a larger portion of a first group of assays and a smaller portion of a second group of assays and wherein the second pattern of assays has a larger portion of said second group of assays and a smaller portion of said first group of assays." However, the Examiner states that "it would have been obvious to include any permutation of first and second group sizes as this is a matter of choice that Bell is capable of performing". Applicant respectfully traverses this obviousness reasoning.

Firstly, in order to practice the claimed invention and as explained above, reagents must be inventoried in at least two reagent servers (Claim 1). Bell's analyzer 10 however, has only one single reactant carousel 26. Bell is therefore inherently incapable of performing Claim 2-4. For this reason alone, the outstanding obviousness rejection over Bell is improper and should be withdrawn.

In addition, as stated above, Bell is attempting to increase the throughput of an analyzer by adding a second reagent transfer station so as to opportunistically place a used cuvette at a wash station so that washing and reactant addition can take place simultaneously. Bell is teaching to increase throughput "without unnecessary addition of equipment such as more wash points, sample or reactant probes, piping or pumps necessary to service them" (Col. 4, lines 8-12). If it was possible to increase throughput by "including any permutation of first and second group sizes as this is a matter of choice

that Bell is capable of performing”, as the Examiner is suggesting, then Bell would have segregated the assays to be performed into “a first pattern of assays having a larger portion of a first group of assays and a smaller portion of a second group of assays and wherein the second pattern of assays has a larger portion of said second group of assays and a smaller portion of said first group of assays” as Applicant has done.

However, what Bell failed to make obvious, and what Applicant has discovered, is that throughput can be increased as claimed, by placing assays into first and second different completion-time patterns, adding a second source of those reagents required to conduct assays in the first pattern of assays, where the first pattern has a larger portion of a first group of assays and a smaller portion of a second group of assays and wherein the second pattern has a larger portion of the second group of assays and a smaller portion of the first group of assays.

Bell only recognizes that different assays may have different completion times:

“dependent upon the assay selected from the menu to be run on a particular sample and its assay sequence, the time necessary to process the cuvettes from additions of the reactant(s), sample, analysis, secondary additions (if required) and washing may vary from assay to assay” (Col 5, lines 20-26)

The general cycle scheduling to accommodate assays having different completion times is described at Col. 8, lines 14-42, and if Applicant’s invention was obvious over Bell, as suggested by the Examiner, the Bell would not have been silent regarding distinct patterns of assays or about the size of groups.

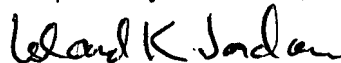
In other words, both Bell and Applicant are seeking to increase analyzer throughput, and Bell is motivated to do so with minimum addition of equipment. If Bell’s analyzer was capable of performing Applicant’s invention, and if it was obvious to “include any permutation of first and second group sizes’ as suggested, then Bell would have done so, in accord with his stated motivation to “inexpensively” increase throughput. Bell’s failure to establish distinct patterns of assays with different sized groups speaks strongly to the non-obviousness of Applicant’s invention.

For these reasons, Applicant submits that the Examiner has failed to provide a convincing line of reasoning as to why Bell did not find the claimed invention as obvious in light of his own teachings. Failing this, a prima facie case of obviousness over Bell has not been established, and it is respectfully requested that the rejection of claims 2-4 under 35 USC 103(a) as being unpatentable over Bell be withdrawn.

Conclusion

Applicant believes that this application contains patentable subject matter and that the foregoing explanation provides a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicant's representative at the number provided below.

Respectfully submitted,



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